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I hereby certify that the attached correspondence comprising:

1. Submission Under 37 C.F.R. 1.114 (9 pages)
2. Request for Continued Examination (RCE) transmittal (in duplicate)
3. Petition and Fee for Extension of Time (in duplicate)
4. Copy of Patent EP 619322
5. 1999 draft Guidance For Industry from the FDA

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